

ARK of MIAMI Inc.
Eduardo Capriles
1235 Washington Ave.
Miami beach FL 33189
Ph: 305 695-1036

Miami, Oct. 22 , 1999

Office of compliance
CHFZ-300
Electriconic Product Reports,
Center for Devices and Radiological Health,
2098 Gaither Road
Rockville Maryland, 20850
AK: Dale Smith / Collin Figueroa

Dear Sirs:

As per your request I'm submitting a new Laser Light show report for the above establishment. For your reference, the original variance for this installation was issued to Pasiely Park Miami on August 14, 1995, variance number 94V-0457, Accession number 94A2317, then two years later a new variance was reissued for this same installation under the Blue Dot Entertainment name which managed the location until January of 1997. Recently the management of this location has been transferred to ARK of Miami Inc. a Company not related in any way to the previous tenants of this location. They are planning on reopening the establishment on November 17th, 1999.

The laser light show equipment and set up will be carefully examined and refurbished to bring it back to its original performance. I'm well familiarized with this equipment and its set up since I have been the Laser Safety officer and operator for this installation since 1995, basically it will be the same show, same certified equipment, same laser safety officer, as well as same hours of operation. However the location of the control booth has been changed as illustrated in attachment 9.1 included in this report.

All original reports, records, manuals, operational logs, etc, are available for inspection.

I'm filling a new Variance application on behalf of ARK of Miami Inc. to comply with regulations for the Administration and enforcement of the Radiation Control for Health and Safety Act of 1968, as they pertain to laser light shows.

I trully appreciate your cooperation in processing this information, if additional reports or any other information is necessary to process this new Variance, please contact Eduardo Capriles at 305 321-6490.

Thank you


Eduardo Capriles
Laser Safety Officer

99V-5197

VAR 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION FOR A VARIANCE
FROM 21 CFR 1040.11(c) FOR A
LASER LIGHT SHOW, DISPLAY,
OR DEVICE

Form 1040-11(c) (Rev. 12-98)
DOCKET NUMBER

NOTE: No laser light show, projection system, or device may claim compliance with 21 CFR 1040.11(c) in design or use without the approval of an application in accordance with 21 CFR 1010.4

INSTRUCTIONS

1. Check all applicable boxes and type or print the requested information.
2. Submit an original and four (4) copies.

1. Mail your application to the Dockets Management Branch (HFD-305), Food and Drug Administration, Room 4-02, 5600 Fishers Lane, Rockville, MD 20857.
2. Only Dockets Number is assigned.

1. NAME OF COMPANY

ARK of Miami Inc.

2. ADDRESS OF COMPANY (Include ZIP Code) (If the company is located outside the United States, include the country name)

1235 Washington Ave, Miami Beach Fla, 33139.

3. NAME AND TITLE OF RESPONSIBLE PERSON

Eduardo Capriles L.S.O.

TELEPHONE NO. (Include area code)

305 321-6490

5. DATE OF SUBMISSION

6-28-99

6. The applicant requests the variance to be in effect for a period of 3 years from the date of issue

(If the variance is for a period of less than 3 years, the applicant must specify the period and the reason for the request.)

7. PRODUCT DESCRIPTION AND USE

a. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S)

Customized LaserPro - Model number 3029C

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED

- ☐ A LASER DISPLAY DEVICE
☐ A PROJECTOR FOR A LASER LIGHT SHOW
☒ A LASER LIGHT SHOW
☐ OTHER (specify) _____

c. ☐ PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. PRODUCT IS INTENDED FOR USE IN A

- ☐ PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE
☐ THEATER
☐ MOTEL/MOTEL BALLROOM OR MEETING ROOM
☐ STORE DISPLAYS
☐ TRADE SHOW OR CONVENTION
☒ DISCOTHEQUE OR NIGHT CLUB
☐ PAVILION
☐ INDOOR ARENA
☐ OUTDOOR ARENA
☐ MUSEUM
☐ OUTDOOR UNENCLOSED AREA
☐ OTHER (specify) _____

e. PRODUCT IS INTENDED TO BE USED

- ☒ AT ONLY ONE (1) LOCATION
☐ AT A VARIETY OF (many) LOCATIONS
☐ OTHER (specify) _____

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION

- ☒ MORE THAN 15 DAYS
☐ MORE THAN 5 BUT NOT MORE THAN 15 DAYS
☐ LESS THAN 5 DAYS

g. TOUR IS INTENDED TO RUN FOR

- ☐ MORE THAN 6 MONTHS
☐ 6 MONTHS
☐ LESS THAN 1 MONTH
☒ NOT APPLICABLE (one-time event)
☐ OTHER (specify) _____

h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS

- ☐ FRONT SCREEN PROJECTIONS
☒ REAR SCREEN PROJECTIONS
☐ HOLOGRAPHIC DISPLAYS
☒ MULTIPLE REFLECTION/DIFFRACTION EFFECTS
☐ AUDIENCE SCANNING (the audience is scanned with a laser beam for safety purposes)
☒ REFLECTIONS FROM STATIONARY MIRRORS OR MIRRORED SURFACES
☒ STATIONARY IRRADIATION OF ROTATING MIRROR BALLS, ETC
☒ SCANNING IRRADIATION OF ROTATING MIRROR BALLS, ETC
☒ FIBER OPTIC PROJECTIONS
☒ FOG, SMOKE, OR OTHER SCATTERING ENHANCEMENT EFFECTS
☒ OTHER (specify) Remote Scanners

8. LASER RADIATION LEVELS

LASER MEDIUM (HeNe, Ar, Kr, etc.)	WAVELENGTHS (nm)	PEAK POWER (Watts)
Argon	520-457nm	5Watts
Krypton	647-676nm	1.2Watts

9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE

N/A

10. REASON FOR REQUESTING VARIANCE

- ☒ COMPLIANCE WITH THE LIMITS OF 21 CFR 1040.11(c) WOULD RESTRICT THE INTENDED USE OF THE PRODUCT BECAUSE COMPLIANCE WOULD LIMIT THE OUTPUT POWER TO THE EXTENT THAT THE DESIRED EFFECTS WOULD NOT BE SUFFICIENTLY VISIBLE
☐ OTHER OR ADDITIONAL EXPLANATION (specify) _____

ARKM
34749
24-1
99A2425

11. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD:
- ☐ IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11(c) IN THAT THE ACCESSIBLE EMISSION LEVEL WOULD EXCEED THE ACCESSIBLE EMISSION LIMITS SPECIFIED IN 21 CFR 1040.11(c).
 - ☐ IT IS PROPOSED TO DEVIATE FROM THE PROVISION OF 21 CFR 1040.11(c) AS FOLLOWS:

N/A

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

- ☐ LASER LIGHT SHOWS AND DISPLAYS ARE ACCEPTED POPULAR MEDIA IN ENTERTAINMENT AND THE ARTS. USE OF POWER LEVELS IN EXCESS OF THE LIMITS IMPOSED BY 21 CFR 1040.11(c) IS NECESSARY TO ACHIEVE THE REQUIRED EFFECTS IN THESE MEDIA.
- ☐ OTHER OR ADDITIONAL ADVANTAGES (describe and explain):

N/A

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (Check as many boxes as apply. In item 14 "Remarks," justify any boxes not checked, using additional sheets as necessary. State any other means of radiation protection that will be used.)

- a. ☒ ALL LASER PRODUCTS, SYSTEMS, SHOWS, AND PROJECTORS WILL BE CERTIFIED TO COMPLY WITH 21 CFR 1040.10 AND THE CONDITIONS OF THIS VARIANCE AND WILL BE REPORTED AS REQUIRED BY 21 CFR 1002.10 AND 1002.12 USING THE REPORTING GUIDES PROVIDED FOR SUCH PURPOSE. THESE ACTIONS WILL BE ACCOMPLISHED PRIOR TO ANY INTRODUCTION INTO COMMERCE.
- b. ☒ EFFECTS NOT SPECIFICALLY INDICATED IN THIS VARIANCE APPLICATION WILL NOT BE PERFORMED. NO OTHER EFFECTS WILL BE ADDED UNTIL AN AMENDMENT TO THE VARIANCE HAS BEEN OBTAINED AND THE REQUIRED REPORTS OR SUPPLEMENTS, AS APPLICABLE, HAVE BEEN SUBMITTED.
- c. ☒ SCANNING, PROJECTION OR REFLECTION OF LASER AND COLLATERAL RADIATION (LIGHT SHOW RADIATION) INTO AUDIENCE OR OTHER ACCESSIBLE UNCONTROLLED AREAS WILL NOT BE PERMITTED EXCEPT FOR DIFFUSE REFLECTIONS PRODUCED BY THE ATMOSPHERE, ADDED ATMOSPHERIC SCATTERING MEDIA, AND TARGET SCREENS.
- d. ☒ LASER RADIATION LEVELS IN EXCESS OF THE LIMITS OF CLASS I WILL NOT BE PERMITTED AT ANY POINT LESS THAN 30 METERS ABOVE ANY SURFACE UPON WHICH PERSONS OTHER THAN OPERATORS, PERFORMERS, OR EMPLOYEES ARE PERMITTED TO STAND OR 25 METERS BELOW OR IN LATERAL SEPARATION FROM ANY PLACE WHERE SUCH PERSONS ARE PERMITTED TO BE OPERATORS. PERFORMERS, AND EMPLOYEES WILL NOT BE REQUIRED OR ALLOWED TO VIEW RADIATION ABOVE THE LIMITS OF CLASS I OR BE EXPOSED TO RADIATION ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c).
- e. ☒ ANY PRODUCT WHICH RELIES ON SCANNING TO MEET ACCESS, EXPOSURE, OR PRODUCT CLASS LIMITS WILL INCORPORATE A SCANNING SAFEGUARD SYSTEM WHICH DIRECTLY SENSES SCANNER MOTION AND WHICH WILL REACT FAST ENOUGH TO PRECLUDE EXCEEDING THE APPLICABLE LIMIT.
- f. ☒ ALL LASER LIGHT SHOWS SHALL BE UNDER THE DIRECT AND PERSONAL CONTROL OF TRAINED, COMPETENT OPERATOR(S). THE OPERATOR(S) WILL:
 - (1) IMMEDIATELY TERMINATE THE EMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION;
 - (2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES, AND
 - (3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF THE OPERATOR.
- g. ☒ THE MAXIMUM LASER PROJECTOR OUTPUT POWER WILL NOT EXCEED THE LEVEL REQUIRED TO OBTAIN THE INTENDED EFFECTS.
- h. ☒ THE PROJECTION SYSTEM (I.E., THE PROJECTOR AND ALL OTHER COMPONENTS USED TO PRODUCE THE LIGHTING EFFECTS) WILL BE SECURELY MOUNTED OR IMMOBILIZED TO PREVENT UNINTENDED MOVEMENT OR MISALIGNMENT. BEAM LIMITERS WILL BE PROVIDED AS AN INHERENT PART OF THE SYSTEM DESIGN TO PREVENT OVERFILLING OF SCREENS, BEAM STOPS, TARGETS, ETC.
- i. ☒ LASER PROJECTORS WILL NOT BE DELIVERED TO ANY OTHER PARTY UNDER AN AGREEMENT OF SALE, LEASE, OR LOAN UNLESS AND UNTIL THE RECIPIENT DEMONSTRATES THAT THEY HAVE A VARIANCE IN EFFECT AT THE TIME OF DELIVERY THAT PERMITS THEM TO PRODUCE LASER LIGHT SHOW INCORPORATING SUCH PROJECTOR.
- j. ☒ IN ADDITION TO THE REQUIREMENTS OF 21 CFR 1040.10(d), THE MANUFACTURER OF LASER PROJECTOR/SYSTEMS WILL PROVIDE TO PARTIES WHO PURCHASE, LEASE, OR BORROW THE EQUIPMENT, ADEQUATE USER INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND WHICH EXPLAIN THE RESPONSIBILITY OF THE RECIPIENT AS AN INDEPENDENT LIGHT SHOW MANUFACTURER TO SUBMIT THE REQUIRED REPORTS AND APPLY FOR AND OBTAIN A VARIANCE FROM FDA PRIOR TO INTRODUCTION INTO COMMERCE OF ANY LASER LIGHT SHOWS.
- k. ☒ THE REQUIREMENTS OF 21 CFR 1002.30(a)(1) AND (2) WILL BE ACCOMPLISHED THROUGH THE USE OF WRITTEN PROCEDURES FOR SETUP, ALIGNMENT, TESTING, AND PERFORMANCE OF EACH SHOW. THESE PROCEDURES WILL BE IN SUFFICIENT DETAIL TO ENSURE COMPLIANCE WITH 21 CFR 1040.10, THE CONDITIONS OF THIS VARIANCE, AND THE CONTROL OF ACCESS TO RADIATION AREAS USING THE PROCEDURES DESCRIBED IN THE ANSI Z136.1 STANDARD FOR THE SAFE USE OF LASERS (AMERICAN NATIONAL STANDARDS INSTITUTE, 1430 BROADWAY, NEW YORK, NY 10018) OR ANY OTHER EQUIVALENT USER CONSENSUS STANDARD AND, WHERE APPLICABLE, STATE OR LOCAL REQUIREMENTS. LASER RADIATION AREAS WHICH CAN CONTAIN RADIATION LEVELS ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c) WILL BE CLEARLY IDENTIFIED BY THE POSTING OF WARNING SIGNS AND/OR RESTRICTING ACCESS THROUGH PHYSICAL MEANS (SUCH AS PRESSURE SWITCHES, PHOTOCELLS, BARRIERS, GUARDS, ETC.). THESE REQUIREMENTS APPLY TO TEMPORARY AREAS (SUCH AS DURING SET-UP AND ALIGNMENT PROCEDURES) AND TO FINAL OR PERMANENT AREAS. THE VARIANCE HOLDER WILL RETAIN THE RECORDS OF THESE PROCEDURES AND THE RESULTS OF ALL TESTS AS REQUIRED BY 21 CFR 1002.31. A COPY OF THE VARIANCE APPLICATION, THE APPROVAL LETTER, CURRENT PROCEDURES, AND RECORDS RELATING TO EACH PARTICULAR SHOW WILL BE WITH THE OPERATOR OR OTHER RESPONSIBLE INDIVIDUAL AND WILL BE MADE AVAILABLE FOR INSPECTION BY FDA AND OTHER RESPONSIBLE AUTHORITIES.

PROPOSED EFFECTS INCLUDING A STATEMENT OF THE MAXIMUM POWER OUTPUT INTENDED SUCH NOTIFICATIONS WILL BE MADE NOT NECESSARILY BE LIMITED, TO

- (1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH OFFICE OF COMPLIANCE (HFZ-312) 8757 GEORGIA AVE., SILVER SPRING 20910, PROVIDING THE INITIAL AND CLOSING DATES FOR FIXED INSTALLATIONS AND THE ITINERARY FOR MOBILE SHOWS IN ACTION UNLESS ALL ASPECTS OF EACH SHOW HAVE BEEN REPORTED AND THE ACCESSION NUMBERS CLEARLY REFERENCED. EACH NOTICE WILL INCLUDE DETAILED DESCRIPTIONS OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE PERFORMED IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE REGULATIONS AND THIS VARIANCE.
- (2) THE FEDERAL AVIATION ADMINISTRATION (FAA) FOR • VY PROJECTIONS INTO OPEN AIRSPACE AT ANY TIME (E.G., INCLUDING SET ALIGNMENT, REHEARSALS, PERFORMANCES, ETC.). IF THE FAA OBJECTS TO ANY LASER EFFECTS, THE OBJECTIONS WILL BE RESOLVED AND ANY CONDITIONS REQUESTED BY FAA WILL BE ADHERED TO. IF THESE CONDITIONS CAN NOT BE MET, THE OBJECTIONABLE EFFECTS WILL BE DELETED FROM THE SKETCH.
- (3) STATE AND LOCAL RADIATION CONTROL OFFICES/AGENCIES FOR ALL SHOWS TO BE PERFORMED WITHIN THEIR JURISDICTIONS REQUIREMENTS OF STATE AND LOCAL LAW WILL BE SATISFIED AND ANY OBJECTIONS RAISED BY LOCAL AUTHORITIES WILL BE RESOLVED OR THE EFFECTS DELETED. (LISTS OF FEDERAL AND STATE OFFICES ARE AVAILABLE FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPON REQUEST)

14. REMARKS

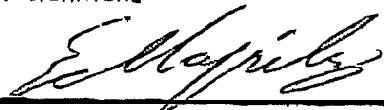
CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete, and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading, or incorrect in any material way. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.12 on the laser equipment and shows. I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

SIGNATURE

16. NAME (Type or Print)

17. TITLE



Eduardo Capriles

Laser Safety Officer